

NOTICE OF ADOPTION OF POLICY STATEMENT

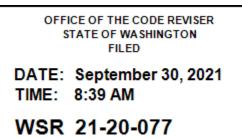
Title of Policy Statement: False or Misleading Statements Concerning Marijuana [Cannabis] Infused Products – Policy Statement Number PS21-05.

Issuing Entity: Washington State Liquor and Cannabis Board

Subject Matter: This policy statement offers the Washington State Liquor and Cannabis Board's position concerning the type of statements that may be considered false or misleading on marijuana [cannabis] product label claims, and establishes a framework to guide false or misleading product label claim evaluation.

Effective Date: September 30, 2021

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Policy Statement

Title:	False or Misleading Statements ConcerningNumber: PS 21-05Marijuana [Cannabis] Infused Products
References:	RCW 66.24.150 RCW 69.50.346
	WAC 314-55-077
	WAC 314-55-105
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Effective Date:	: September 30, 2021
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RCW 34.05.230 – Interpretive and policy statements

(1) An agency is encouraged to advise the public of its current opinions, approaches, and likely courses of action by means of interpretive or policy statements. Current interpretive and policy statements are advisory only. To better inform the public, an agency is encouraged to convert long-standing interpretive and policy statements into rules.

INTRODUCTION

Throughout this document, the term "cannabis" is used in the context of the statutory meaning of "marijuana" as defined in chapter 69.50 RCW.

This policy statement is intended to define and scope what types of statements may be false or misleading, to the extent possible, and establish a framework to guide false or misleading product label claim evaluation.

This policy statement supersedes and replaces previous agency guidance concerning this topic.

SUMMARY

WSLCB's Licensing Division's Packaging and Labeling team have received multiple submissions for packaging and labeling of both solid and liquid cannabis infused edible products containing reference to alcohol drinks and imagery commonly known to be associated with alcohol. Current rule and associated guidance seek to address this concern. Federal law prohibits the use of false or misleading statements in labeling for drugs, cosmetics, tobacco products, foods, supplements, and alcoholic beverages. Similarly, RCW 69.50.346 provides that labeling for marijuana concentrates, usable marijuana or marijuana infused products may not be false or misleading. This Policy Statement confirms that WSLCB continues to align with federal standards in determining whether cannabis product labeling is false or misleading.

BACKGROUND

On December 12, 2018, board interim policy (BIP) 07-2018 was issued to further clarify the phrase "false and misleading" regarding packaging and labeling of marijuana-infused products, and to address concerns regarding packaging and labeling designed to mimic, imply, or reference a product containing alcohol. The interim policy was designed to clarify the phrase "false or misleading" in WAC 314-55-105 for licensees, protect the public, and to reduce risk of accidental exposure to marijuana.

BIP 07-2018 provided that to comply with the labeling requirements described in <u>WAC</u> <u>314-55-105</u>, labels affixed to a container or package containing useable marijuana, marijuana concentrates, and marijuana infused products sold at retail stores in Washington State must not mimic, imply, represent or contain any statement, depiction, illustration, design, brand, or name of a product containing alcohol.

BIP 07-2018 also provided that product label design mimicking or implying that a marijuana product contains alcohol was considered false and misleading and increased public safety risk. However, rule did not prohibit certain words or references to be used, such as "non-alcoholic," "does not contain alcohol," "not a beer", "not a wine," "not a spirit", and "0%ABV."

BIP 07-2018 was rescinded on December 18, 2019 when final rules were adopted that substantially revised WAC 314-55-105 and implemented Engrossed Senate Substitute Bill (ESSB) 5298 regarding the allowance of additional information on labels of cannabis infused products. Rules became effective January 1, 2020 and did not incorporate the language from BIP 07-2018. Instead, the adopted rules referred to 21 C.F.R. Sec 101.18(a) concerning false or misleading statements. Specifically, 21 C.F.R. Sec 101.18(a) provides that, "...among representations in the labeling of a food which *render such food misbranded is a false or misleading representation with respect to another food or a drug, device, or cosmetic.*" (Emphasis added).

WSLCB prepared and published an extensive packaging and labeling guide designed to assist and support licensee compliance with the new rules. The guide provides the following description of false or misleading statements, incorporating the language of both the federal code and rescinded BIP 07-2018:

False or Misleading Statements

Title 21, Volume 2, 21 CFR 101.18 Misbranding of food

Among representation on the labeling of food which render such food misbranded is a false or misleading representation with respect to another food or a drug, device, or cosmetic.

A false or misleading statement is one that is either not true, or a statement that implies something about the product or package that is not true. Labels affixed to a container or package containing usable marijuana concentrates, and marijuana infused products sold at retail in Washington State must not:

- Mimic, imply, represent or contain any statement, depiction, illustration, design, brand, or name of a product containing alcohol.
- Be designed similarly to products or words that refer to products that are commonly
 associated or marketed to persons under twenty-one years of age.
- Have product label designs that mimic or imply that a marijuana product contains alcohol, are false and misleading, and increase public safety risk. Use of the following words or references does not permit the design to mimic or imply the product contains alcohol. Words or references include, but are but not limited to: non-alcoholic, does not contain alcohol, not a beer, not a wine, not a spirit, or 0%ABV

Despite both the rule description and the guidance incorporating the rescinded BIP language, the Licensing Division's Packaging and Labeling team received multiple submissions for packaging and labeling of both solid and liquid cannabis infused edible products containing reference to alcohol drinks and imagery commonly known to be associated with alcohol.

STATUTORY AUTHORITY

RCW 66.24.150(3)(d) provides that holders of a license to manufacture liquor may not mix or infuse THC, CBD, or any other cannabinoid into any products containing alcohol.

RCW 69.50.346 describes required labeling content for all marijuana concentrates, usable marijuana, or marijuana-infused products sold at retail.

RCW 69.50.346(3)(a) provides that labeling for marijuana concentrates, usable marijuana or marijuana infused products may not be false or misleading.

REGULATORY AUTHORITY

WAC 314-55-077(6) describes WSCLB cannabis recipes, product, packaging and labeling approval process and requirements.

WAC 314-55-105 describes marijuana product packaging and labeling.

ANALYSIS

Federal law prohibits the use of false or misleading statements in labeling for drugs, cosmetics, tobacco products, foods, supplements, and alcoholic beverages.¹ It also prohibits marketing of food and dietary supplements containing cannabis.² The FDA has not approved any food or drug containing cannabis.³ However, cannabis and products containing cannabis, including food products, are legal and may be produced, processed and sold in Washington State in facilities licensed by the WSLCB.

Cannabis product labeling laws were amended during the 2019 legislative session by Engrossed Substitute Senate Bill (ESSB) 5298 (Chapter 393, Laws of 2019). Among other things, the legislation provided that a label or labeling on a product container including marijuana concentrates, usable marijuana, or marijuana infused products sold at retail may not be false or misleading. ⁴ The term "false or misleading" is not defined in statute, nor does it appear anywhere else in the Controlled Substances Act. As a result, the WSLCB turns to federal statute and regulation for guidance.

Federal Treatment of "False or Misleading"

The FDA's efforts to protect consumers from false or misleading claims are conducted in a complex and challenging legal and regulatory environment, and two-pronged. The first prong concerns false or misleading claims concerning products. The FDA continues to work toward providing clear guidance on the scientific or other support needed to prevent false or misleading information on labels that make structure or function claims. However, the FDA does not have express legal authority to compel a company to provide such information, even though there is a general statutory requirement that labeling not be false or misleading.⁵ In contrast, the Federal Trade Commission (FTC) which is responsible for protecting consumers from false advertising generally, has the statutory authority to compel companies to provide support. FTC officials note that the Commission would have difficulty taking enforcement actions against companies for alleged structure or function claims on food labels and in advertisements without access to companies' proprietary market and scientific research.⁶

The second prong concerns false or misleading labeling itself, or the outer packaging of a product representing what the product *is* rather than what the product may *do*. For example, 21 C.F.R. Sec.101.18(a) provides that among representations in the labeling of a

5 KCW 69.50.326(3)

¹ Federal Food, Drug and Cosmetics Act (CITE)

² 21 U.S.C. 321

³ FDA Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidiol (CBD)(https://www.fda.gov/newsevents/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-productsincluding-cannabidiol-cbd) ⁴ RCW 69.50.326(3)

⁵See 21 C.F.R. Sec.101.18(a)

⁶ UNITED STATES. GOVERNMENT ACCOUNTABILITY OFFICE, FOOD LABELING : FDA NEEDS TO REASSESS ITS APPROACH TO PROTECTING CONSUMERS FROM FALSE OR MISLEADING CLAIMS : REPORT TO CONGRESSIONAL COMMITTEES (U.S. Govt. Accountability Office) (2011), INSERT-MISSING-URL (last visited Aug 13, 2021)

food which render such food misbranded is a false or misleading representation with respect to another food or a drug, device, or cosmetic. "Misbranding" is a term or art that encompasses a series of individual statutory prohibitions. Under the Food, Drug and Cosmetics Act (FDCA) misbranding provision, a good (including bottled water) purporting to be a food for which a definition and standard of identity has been prescribed is deemed "misbranded" if" (1) it does not conform with the applicable standard of identity; or (2) its label does not bear the name of the good specified in the definition and standard.⁷

These misbranding categories are interrelated. Characteristics of the labels that are required or permitted by specific statutory provision are not considered "false or misleading" under federal law. However, if certain characteristics of a label *are* required or permitted, and thus by definition not false or misleading, the remainder of the label must still comply with federal statute and not be "false or misleading in any particular."⁸

For example, on May 25, 2016, the FDA issued guidance that it is false or misleading to describe sweeteners made from sugar cane as "evaporated cane juice."⁹ The FDA explained that the term "cane juice" —as opposed to cane syrup or cane sugar—calls to mind vegetable or fruit juice, ¹⁰ which the FDA said is misleading as sugar cane is not typically eaten as a fruit or vegetable.¹¹ The FDA concluded that the term "evaporated cane juice" fails to disclose that the ingredient's "basic nature" is sugar.¹² The FDA therefore advised that "evaporated cane juice' is not the common name of any type of sweetener and should be declared on food labels as 'sugar,' preceded by one or more truthful, non-misleading descriptors if the manufacturer so chooses."¹³

Additionally, the Nutrition Labeling and Educational Act of 1990 (NLEA) contains an express preemption provision that prohibits states from enacting label regulations and requirements that are not identical to the FDCA requirements.¹⁴ Per the preemption provision, state labeling laws will be preempted if they set forth requirements that are "affirmatively different than the federal requirements."¹⁵

- ¹² Guidance for Industry, Ingredients Declared as Evaporated Cane Juice, May, 2016, available
- at http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/ucm181491.htm.

⁷ 21 U.S.C.A. § 343(g); In re PepsiCo, Inc., Bottled Water Marketing and Sales Practices Litigation, 588 F. Supp. 2d 527 (S.D. N.Y. 2008).

⁸ <u>21 U.S.C.A. § 343(g)</u>; In re PepsiCo, Inc., Bottled Water Marketing and Sales Practices Litigation, 588 F. Supp. 2d 527 (S.D. N.Y. 2008).

⁹ Guidance for Industry, Ingredients Declared as Evaporated Cane Juice, May, 2016, available

at http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/ucm181491.htm. ¹⁰ 21 C.F.R. § 120.1(a).

¹¹ U.S. Department of Agriculture, Center for Nutrition Policy and Promotion, *Added Sugars*, January 7,2016, available at http://www.choosemyplate.gov/added-sugars.

¹³ Guidance for Industry, Ingredients Declared as Evaporated Cane Juice, May, 2016, available

 $at\ {\tt http://www.fda.gov/food/guidanceregulation/guidancedocuments regulatory information/ucm181491. {\tt htm.}$

¹⁴ See <u>21 U.S.C. § 343-1(a) (2012)</u> (creating provision wherein federal label laws preempt state label laws). The NLEA prohibits states from directly or indirectly establishing food label requirements that are not identical to the FDCA's food label requirements.

¹⁵ Jennifer L. Pomeranz, *Litigation To Address Misleading Food Label Claims and the Role of the State Attorneys General_26* REGENT U.L. REV. 421, 429 (2014) (noting preclusion of state label laws "affirmatively different" than federal requirements) [hereinafter *Litigation To Address Misleading Food Label Claims*]; Termini, *supra* note 4, at 102 (stating preclusion of state

POLICY STATEMENT

The WSLCB sought to define "false and misleading" statements through policy (BIP 07-2018) which was narrowly designed to address cannabis products that may mimic, imply, represent or contain any statement, depiction, illustration, design, brand, or name of a product containing alcohol. However, ESSB 5298, subsequently codified as RCW 69.50.346 broadened cannabis labeling standards by providing that all cannabis product labels were not to be "false or misleading." In doing so, this places the WSLCB in the position of the FDA to establish criteria for evaluation of cannabis product labels to determine whether labeling is false or misleading.

False or misleading statements are two-pronged. The first prong is associated with structure or function claims concerning medically compliant cannabis products as described in WSLCB Policy Statement PS-21-04, where claims about the effect of a product on the structure or function of the body are discussed. The second concerns cannabis product labeling – both adult use and medically compliant products – and whether the product labeling is false or misleading through the depiction of another food, beverage, or flavor associated with a non-cannabis product such as alcohol.

Thus, consistent with RCW 69.50.346, and in alignment with 21 U.S.C.A. § 343, cannabis product labeling will be considered false or misleading if any of the following apply:

- Product labeling is false or misleading in any particular;
- The product is offered for sale under the name, identity or characteristics of another food or beverage or mimics another food or beverage, or the characteristics of another food or beverage, such as an alcohol product;
- The product is an imitation of another food or beverage, unless the label bears, in type of uniform size and prominence, the word "imitation" and, immediately thereafter, the name of the food or beverage imitated; or
- If its container is so made, formed or filled as to be misleading (for example, shaped like a martini glass or champagne bottle); or
- If the packaging, labeling, or both of a liquid or solid cannabis product contain an image or images of alcohol glasses or bottles.

regulations conflicting with certain enumerated FDCA sections, but not all). But see Termini, supra note 4, at 104-05 (asserting state action still encouraged to complement federal enforcement of regulations).